APPENDIX N BULK MILK TANKER SCREENING GENERAL REQUIREMENTS

Items in bold must be recorded and available for review. All records, including test print-outs, must be kept for at least two years.

Personnel

- Industry Analysts (IA's) are trained and training records are on file in the lab. The Industry Supervisor or Certified Industry Supervisor must report[1] any changes in the list of Industry Analysts to the LEO and provide records of IA training to the LEO at that time.
  - **IA's must be adequately trained by the Industry Supervisor or Certified Industry Supervisor before testing milk for processing. DOCUMENT THIS TRAINING.**
  - After initial training, each IA must demonstrate competency at least once every two years by satisfactorily participating in the annual split samples or satisfactorily participating in an on-site inspection. **Maintain copies of split sample reports and on-site inspection reports.** NOTE: IA's are strongly encouraged to participate in every set of split samples and every on-site inspection.
- **Industry Supervisors (IS's) and Certified Industry Supervisors (CIS's) are trained by the state LEO and training records are on file in the lab.**
  - **The laboratory must notify[1] the LEO within 30 days of any change of IS or CIS and schedule a date to receive training from the LEO.**

[1] Use Attached Industry Laboratory Drug Residue Analyst List

Sampling Requirements and Recordkeeping

- **Measure and record the temperature of the bulk milk tanker.**
- Prevent contamination of the sample with disinfectants from hands or other sources.
- Obtain a representative sample and a temperature control (TC) for drug residue testing – **record the time the sample is collected.**
  - A temperature control (TC) consists of the same volume of raw milk as the sample in the same type of container and is collected at the same time the sample is collected.
- Transport sample and TC to testing location immediately, preferably on ice to maintain temperature.

- **Record the identity of the bulk milk pickup tanker being tested, including the BTU number(s) of the farms present on the bulk milk pickup tanker.**
- **Record the name of the person doing the test.**
- **Record the date and the time the sample was tested (Time, Month, Day, & Year).**
- Samples are tested within 72 hours of initial collection.
- If confirmation test is necessary, complete the confirmation within 72 hours of initial collection.
- **Record the time, date and temperature of samples when they are received and tested.**
- Determine sample temperature by inserting a pre-cooled thermometer into the temperature control. If you are using an electronic/digital thermometer probe, pre-cooling is not necessary.
- If raw milk exceeds 4.4°C on receipt do not test (EXCEPTION: Samples may be received at 7°C if time of receipt is less than 3 hours from the time of collection and receipt temperature is equal to or less than the collection temperature.)

Work Area

- Ample working space and utilities.
- Work space is clean, well ventilated, and reasonably free from dust and drafts.
- Test kit is used in the temperature range specified by manufacturer.
- Work space has adequate lighting, at least 50 foot-candles at working surface.

Storage Space

- Cabinets, drawers, and shelves are adequate.
- Work areas are neat, clean and orderly.

Thermometers Used for Testing and for Laboratory Equipment

- NIST-traceable thermometer with manufacturer's certificate, **checked at ice point at least once a year.**
- [SCREENING LABS] Test and equipment thermometers have increments no greater than 1.0°C
- [NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISOR LABORATORIES] Test and equipment thermometers have increments no greater than 0.5°C.
- **Calibrate each thermometer in the laboratory with the NIST-traceable thermometer at least once a year (including electronic thermometers).**
  - ◊ All thermometers are accurate to ±1C.
  - ◊ Calibration results are recorded in a permanent log book.

- ◊ **Thermometers have tags with the calibration date, identification name or number, temperature checked and correction factor. If there is no correction factor, mark the tag ±0.0°C.**
- ♦ Dial thermometers not permitted.
- ♦ The following are examples of thermometers that must be calibrated with the NIST thermometer at least once a year:
  - ◊ Test kit heater block/incubator thermometer.
  - ◊ Refrigerator thermometer.
  - ◊ Freezer thermometer (Send the freezer thermometer to a calibration shop for annual calibration if your NIST thermometer does not read -15°C.)
  - ◊ Thermometers for checking sample temperature controls.

Refrigerator

- ♦ Size adequate for workload.
- ♦ Maintains temperature at 0-4.4°C.
- ♦ Reagents are stored as recommended by manufacturer instructions.
- ♦ Food not stored.
- ♦ [SCREENING LABS] Install one thermometer on the top shelf and one thermometer on the bottom shelf. The bulb of each thermometer must be immersed in liquid. **Read and record the temperatures from each thermometer once a day – Two temperatures recorded for each day.**
- ♦ [NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISOR LABORATORIES, AM and PM] Install one thermometer on the top shelf and one thermometer on the bottom shelf. The bulb of each thermometer must be immersed in liquid. **Read and record the temperatures from each thermometer once in the morning and once in the afternoon – Four temperatures recorded for each day.**
- ♦ [NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISOR LABORATORIES] Refrigerator is dedicated for milk work only.

Freezer for Storing Frozen Test Controls

- ♦ Adequate size for lab workload.
- ♦ Maintains temperature at -15°C or below.
- ♦ No food stored.
- ♦ **Record temperature at least once a day.**
- ♦ [NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS] Dedicated for milk work only.

Electronic Analytical Balance for Pipet Calibration

- Balance is sensitive to 0.001g.
- The laboratory must have NIST Class S or S1 weights or ASTM Type 1, 2 or 3 weights in the following increments: 1 mg, 10 mg, 50 mg, 100 mg, 500 mg and 1 g.
- **Check balance quarterly (every 90 days) with the weights listed above.**
- **Have balance checked once a year by a qualified service representative.**
- Maintain records.

Fixed Volume Pipettors

- **Calibrate each pipettor quarterly (every 90 days).**
- Pipettors that measure less than 1.0 mL must be calibrated on the analytical balance by weighing ten (10) consecutive portions dispensed from the pipet. Use a separate tip for each weighing. Pre-wet the tip before each weighing.
  - The average of all 10 weighings must be ±5% of each pipettor's specified delivery volume.
  - For example, the average of 10 weighings for a 300µL pipettor must be 300±15 mg (285 to 315mg)
- Pipettors that measure ≥1.0 mL or more must be calibrated by using a Class A graduated cylinder.
  - The average of all 10 volume checks must be ±5% of each pipettor's specified delivery volume.
  - For example, the average of 10 volume checks for a 5 mL pipettor must be 5.0±0.25 mL (4.75 to 5.25 mL)
- **Each pipettor must be etched or otherwise marked with a unique identification and tagged with the calibration date.**
- Pipettors may be calibrated either on-site or at another approved laboratory.

Test Kit Performance Testing

- **Run a positive and negative control with each new lot of kits on the day the kits are received. The new lot of kits must give appropriate results and the records must be maintained on a separate log form (not on the daily testing log). Record analyst ID, date, kit lot number, lot numbers of positive and negative controls and test results[2]. Attach the test result print-out to the log sheet.**
- **If available from manufacturer, check instrument calibration check devices DAILY and before testing positive and negative controls when following up positive results. Check devices must give appropriate results, if not, discontinue testing, contact State regulatory and seek technical assistance, records maintained**
- Run a negative and positive control DAILY on each day that samples are tested. The controls must give appropriate results, if not, re-test the controls. If necessary,

prepare new controls. If the problem persists discontinue all sample testing, contact State regulatory and seek technical assistance. **Maintain records of the analyst ID, lot numbers of the controls and test results for the daily positive and negative control checks.**

- If more than one analyst performs analysis have different analyst run the daily positive and negative controls on rotational basis.

[2] An example of a form to record the Test Kit Suitability Check is attached.

Positive Control Performance Testing

- **Test each new lot of positive control on the day of receipt with a previously tested test kit. The positive control must give an appropriate result and the record must be maintained on a separate log form (not on the daily testing log). Record analyst ID, date, kit lot number, lot number of positive control and test result[3]. Attach the test result print-out to the log sheet.**

[3] An example of a form to record the Positive Control Suitability Check is attached.

Reporting and Records

- **Report test results as positive (+) for beta-lactam drugs, or as Not Found (NF).**
- **Record the name of the test that was performed and the interpretation of the results for the samples and controls.**

Miscellaneous

- **Material safety data sheets (MSDS) must be on file and accessible to the lab.**
- **Current FDA survey forms (2400 forms) must be available in the laboratory.**
- **Virginia Department of Agriculture "Positive Animal Drug Residue Report" form (9/12/02) must be available in the laboratory.**
- **Split sample reports for current year and previous year must be available in the lab.**

CONFIRMATION TESTING

(If test kit indicates a positive result, confirmation must be completed, when necessary, within 72 hours of initial collection.

Determining If a Sample Is Presumptive Positive

- A Presumptive Test may be performed by an Industry Analyst.
- If a sample is positive on the first test, the same analyst must test the same sample again in duplicate along with a positive and negative control. Use the same lot number of test kit used for the initial positive sample.
- If the positive and negative controls give the appropriate results, report sample results and contact state regulatory. Screening laboratories will stop testing at this point and turn sample over to State regulatory.
- If either the positive or the negative controls or both do not give appropriate results, re-test the controls and samples. If the problem persists contact state regulatory and seek technical assistance
- **Maintain copies of all Presumptive Positive Test results.**

Determining If a Sample Is Screening Test Positive (Load Confirmation)

- A Screening Test Load Confirmation may be performed only at a Certified Industry Supervisor Lab or an NCIMS Certified Lab. The Screening Test Load Confirmation may be performed only by a Certified Industry Supervisor or a Certified Analyst.
- If a sample is Presumptive Positive (as outlined above), test the same sample again in duplicate along with a positive and negative control. Use the same lot number of test kit used for the presumptive positive sample.
- If the positive and negative controls give the appropriate results, report sample results. If one or both of the duplicate tests is positive, the sample is a Screening Test Positive Load Confirmation. Report the results to state regulatory.
- If either the positive or the negative controls or both do not give appropriate results, re-test the controls and samples. If the problem persists contact state regulatory and seek technical assistance
- **Maintain copies of all Screening Test Load Confirmation results.**

Testing Producer Samples After a Positive Screening Test Load Confirmation

- Producer sample testing/trace back may be performed only at a Certified Industry Supervisor Lab or an NCIMS Certified Lab. Producer sample testing/trace back may be performed only by a Certified Industry Supervisor or a Certified Analyst.
- If there is no TC with the producer samples, aliquot samples for testing and measure temperature using one of the producer samples.
- Do not accept producer sample containers that are over ¾ full.

- Perform an initial single test on each producer sample along with a positive and negative control. If any producer sample is positive the sample is SUSPECT and that/those sample(s) must be retested.
- The same sample(s) is re-tested by the same analyst using the same test kit in duplicate along with a positive and negative control.
- If the positive and negative controls give the appropriate results, report sample results. If one or both of the duplicate tests is positive, the producer sample is a confirmed positive. It is an Appendix N violation and the producer is subject to regulatory action.
- **Maintain copies of all Producer Sample Confirmation results and forward the original to State Regulatory.**

REFERENCES

This training material was prepared using the following documents:

1. Appendix N Bulk Milk Tanker Screening Test Form, General Requirements, FDA Survey Form APPN/GENREQ, Rev. 3/99.
2. FDA LQAT Power Point Presentation titled "Appendix N Bulk Milk Tanker Screening Test Form General Requirements" presented at the 2004 LEO Workshop.
3. "Evaluation of Milk Laboratories", 2003 Revision, USDHHS, PHS, FDA LQAT
4. "Interpretation of Pasteurized Milk Ordinance (PMO) Appendix N Testing Program for Drug Residues, M-a-86, Revision 3, July 23, 2001. FDA CFSAN, www.cfsan.fda.gov/~ear/m-a-86.html
5. Pennsylvania Department of Agriculture Approved Laboratory/Facilities, Current Quality Control Forms, www.agriculture.state.pa.us/agriculture/cwp/view.asp?a=3&q=129216

INDUSTRY LABORATORY
DRUG RESIDUE ANALYST LIST

INDUSTRY LAB NAME _____ **DATE:** _____

MAILING ADDRESS _____ **TELEPHONE # (____)** _____

_____ **FAX # (____)** _____

E-MAIL ADDRESS _____

DRUG RESIDUE TEST(S) USED _____

	STATUS: CHECK ONE BELOW			TITLE: CHECK ONE BELOW			
ANALYST NAME **Attach Copy of Each Industry Analyst's Training Record to This Form**	**RESIGNED**	**NEW**	**NO LONGER TESTING MILK**	**CERTIFIED INDUSTRY SUPERVISOR**	**INDUSTRY SUPERVISOR**	**BACK-UP SUPERVISOR**	**INDUSTRY ANALYST**

Any change in analyst status (new, resigned, no longer testing milk, etc.) must be sent to the Laboratory Evaluation Officer immediately. Test methods cannot be changed without prior approval. Contact LEO's Barbara Hartlage, (276) 228-5501; DeDe Bache-Shumate (540) 347 6385; or Eileen Q. Sanders, (804) 648-4480, ext 383.

TEST KIT SUITABILITY CHECK FOR DRUG RESIDUE TESTING

LABORATORY NAME:_____

TEST METHOD USED: _____

R = Results observed (number on print-out) I = Interpretation (Pos or NF)

DATE RECEIVED	TEST KIT LOT NUMBER	EXPIRATION DATE	DATE TESTED	POS CONTROL LOT #				ANALYST
				NEG CONTROL ID # (TANKER # OR OTHER IDENTIFICATION)				
				CONTROL RESULTS/INTERPRETATION				
				R POS CONTROL I		R NEG CONTROL I		

CHARM SL/SL6 CALIBRATOR READINGS	**CALIBRATOR SERIAL NUMBER**	IDEXX SNAP CHECK SET READINGS	**CHECK SET SERIAL NUMBER**	**ATTACH PRINT-OUT OF RESULTS**
HIGH		POS RANGE		
LOW		NEG RANGE		
		POS READING		
		NEG READING		

POSITIVE CONTROL SUITABILITY TEST

LABORATORY NAME:_____

TEST METHOD USED: _____

	POSITIVE CONTROL IFORMATION					TEST KIT INFORMATION				TEST RESULTS		
DATE	POS CONTROL MANUFACTURER	POS. CONTROL LOT #	MANUF. EXP. DATE	DATE CONTROL PREPARED	PREPARED CONTROL EXP DATE	TEST KIT USED	TEST KIT LOT #	TEST KIT EXP. DATE	DATE TEST KIT LOT TESTED	POS CONTL. RESULTS (NUMBER ON TAPE)	POS CONTL. INTERPRETATION (POS/NF)	ANALYST

ATTACH PRINT-OUT OF RESULTS